Cost-effectiveness evaluation of powered staplers in video assisted thoracoscopic lung resection procedures

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Research Article

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Abstract

Background:

Video-assisted thoracic surgery (VATS) is currently established as the preferred approach for surgical resection of early-stage lung cancer and has been recommended by multiple clinical associations. This study aimed at evaluating the cost-effectiveness of powered vs manual staplers in video-assisted thoracic surgery (VATS) for lung lobectomy in support of hospital-based health technology assessment.

Methods:

Clinical and economic comparisons between powered endoscopic staplers (PES) and manual endoscopic staplers (MES) in VATS lobectomies were conducted using a decision tree model from the perspective of hospital administrators. Prolonged air leak (PAL) was selected as the surgery complication for the model. Clinical performances measured by PAL rates for the staplers were obtained from a targeted literature review. The economic parameters used in the model were based on results from real-world data analysis in China. The outcomes used in the cost-effectiveness analysis were total costs and post-discharge 6-month reoperation rates. Cost-effectiveness was measured by the incremental cost per reduction of reoperation. Model stability was evaluated using both one-way sensitivity analysis and probabilistic sensitivity analysis (PSA).

Results:

Deterministic calculation results showed powered staplers dominated manual stapler, with lower per-episode costs (CNY 83,487 for PES vs CNY 86,239 for MES) and lower reoperation rates (0.54% for PES vs 0.63% for MES). One-way sensitivity analysis and PSA results further supported that the powered stapler was the dominant strategy for VATS lobectomies.

Conclusions:

The cost-effectiveness analysis demonstrated powered staplers are cost-effective compared to manual staplers in VATS lobectomies.

Introduction

Lung cancer is the leading cancer type in both incidence and mortality around the world. The GlobalCan 2018 report estimated 1.7 million new lung cancer cases globally in 2018(1). Chen et al. reported the age-standardized mortality rate for lung cancer was 28.49 per 100,000 in China. The rates in men and women were 40.30 per 100 000 and 17.13 per 100 000, respectively(2).

One common treatment for lung cancer is surgical resection. Video-assisted thoracoscopic surgery (VATS) was introduced in the early 1990s as a minimally invasive, alternative approach to open thoracotomy surgery. The VATS approach provides advantages such as a shorter duration requiring a chest tube during operation, fewer complications, less postoperative pain, and similar clinical results for tumor eradication when compared with traditional thoracotomy(3). VATS is currently established as the preferred approach for

surgical resection of early-stage lung cancer and has been recommended by the American College of Chest Physicians (ACCP), the National Comprehensive Cancer Network (NCCN), and the European Society for Medical Oncology (ESMO)(4). When performing VATS, endoscopic linear stapling devices that both cut and saw are one of the more skill-demanding techniques. These staplers can be broadly divided into two groups based on their activation mechanism: manual endoscopic staplers (MES) and electrical power-controlled endoscopic staplers (PES). MES and PES differ in price and design. These differences can potentially impact both the clinical and economic outcomes of VATS.

Health technology assessment (HTA) is a multidisciplinary field of applied research aimed at providing high-quality information about the clinical effectiveness or efficacy, cost-effectiveness, and a broader impact (including social and ethical implications) of health technologies (drugs, medical technologies, and health interventions) to support and inform those who make decisions about health policy and purchasing, health services organization and management and clinical practice(5). HTA is increasingly being adopted at the hospital level to support management decisions regarding devices, drugs, and procedures. Historically, HTA was not regarded as a critical tool for healthcare decision-making in low- and middle-income countries, including China(6). Recent hospital payment reforms in China forced hospital administrators have focused on value-based healthcare delivery. As a class of high-cost consumable devices, endoscopic staplers are increasingly being reviewed as candidates for cost-control. Based on our literature review, there is no published research available to support the cost-effectiveness assessment of MES vs PES in China. In this study, we aim to bridge the evidence gap by conducting a cost-effectiveness analysis of PES vs MES in VATS lobectomies.

Methodology

Modeling structure

In this study, a decision tree model was built to compare the cost-effectiveness of PES vs MES in VATS lobectomies from the perspective of China hospital administrators. Our decision tree structure was shown in Figure 1. The modeled population was composed of adult Chinese lung cancer patients requiring VATS lobectomies in tertiary hospitals in China. The two interventions compared were VATS lobectomies using two different types of endoscopic staplers: PES and MES. The model assumes the surgery team had the same levels of skill and experience regardless of the choice of staplers. Prolonged air leaks are the most prevalent and costly surgery complications for VATS lobectomies. Our model explicitly tracked the incidence of PAL events. In addition to calculating total costs for the economic outcome, the 6-month re-operation rates post-discharge were measured for the clinical effectiveness outcome.

The entire evaluation period of the cost-effectiveness analysis (CEA) was less than 7 months, including both the initial surgery period and the post-discharge follow-up period. Discounting would not create any material impact for this analysis. No discounts for cost or outcome were explicitly considered. The final CEA analysis decision was based on the incremental cost-effectiveness ratio (ICER), expressed as cost per reduction of re-operation. The willingness to pay (WTP) threshold for ICER values in this analysis is set to be the average total costs of a single reoperation event.

The decision tree was implemented using TreeAge Pro (version 2014)(7). The deterministic analysis was performed for the base case scenario. One-way sensitivity analysis (OWSA) and probabilistic sensitivity analysis (PSA) were also used to evaluate the stability of model results against input variable uncertainty.

Clinical Inputs

Two types of clinical inputs were used for the CEA model to capture the peri-operative and short-term efficacies. The peri-operative efficacy of staplers in VATS lobectomies was measured by PAL rates reported in a published clinical study. A head-to-head comparison of PAL rates among one type of MES and two types of PES was reported by Xiao et al in 2019(3). The outcomes reported by Xiao et al were based on retrospective study of VATS lobectomy surgeries performed by a single surgeon in a large tertiary hospital in China. We combined the two PES data sets as the efficacy input for PES in our CEA model. The final PAL rates were 25.3% and 6.4% for MES and PES, respectively. Table 1 details the sample size and PAL cases. Beta distributions were used to model the probabilities of peri-operative PAL for the two intervention strategies in PSA.

The short-term efficacies of the staplers were measured using 6-month post-discharge re-operation rates. Electronic medical records (EMR) retrieved from 20 tertiary hospitals in China were used to estimate the six-month reoperation rates. The participating hospitals were selected based on their geographic location: five in the north (Beijing, Jinan, Shenyang), 3 in the south (Guangzhou, Fuzhou, Kunming), 4 in the east (Shanghai, Nanjing), 4 in the west (Chongqing, Lanzhou, Wulumuqi), and 4 in the middle (Wuhan, Xi'an). Patient inclusion criteria are: 1) 18 years or older, 2) diagnosed with lung cancer, 3) received a VATS lobectomy, and 4) surgery times were between 1/1/2018-6/30/2018. Robotic surgeries were excluded from the analysis. Patients with incomplete medical records or received more than one surgery in the same episode of care were also excluded. Eligible patients were divided into two groups based on the occurrence of PAL in the peri-operative period. Post-discharge re-operation rates were calculated separately for the PAL and no PAL groups.

Cost Inputs

Direct costs were derived from the same real-world EMR data set described above and followed the same inclusion/exclusion criteria. Costs were reported using Chinese Yuan (CNY). Except for the stapler and cartridge costs, all other cost items in PSA were assumed to have Gamma distributions defined by the observed means and standard deviations.

The peri-operative costs included all inpatient costs such as pharmacy costs, anesthesia costs, lab costs, medical service costs, etc. Both the means and standard deviations for total costs and categorical costs are reported in Table 2. The stapler and cartridge costs were calculated separately based on the prices listed on the government-sponsored hospital procurement platform. The model assumed each VATS lobectomy used one PES with 6.5 cartridges or one MES with 6.94 cartridges based on the average stapler to cartridge ratio per VATS lobectomy from a published real-world retrospective study reported by Xiao et al. The detailed product information and the costs of staplers and cartridges are reported in Table 3.

Readmission for re-operation is rare. We only observed 10 cases of re-operation in the EMR dataset. We calculated the mean and standard deviation of the total readmission costs based on all 10 cases without further stratifying them by peri-operative PAL status.

Results

A total of 1681 patients were included in the analysis. 297 patients experienced PAL in the peri-operative period, out of which 3 patients were readmitted for reoperation within six months after discharge. Only 7 out of the 1384 no-PAL patients had reoperation within the same period post-discharge. Peri-operative costs, excluding stapler and cartridge costs, are provided in Table 2. The re-operation rates for the CEA analysis were also included in Table 1. Reoperation costs were estimated by combining the total costs from all ten patients who underwent reoperation regardless of their PAL status. The mean total all-inclusive reoperation cost was CNY 57,669.22 with a standard deviation of CNY 10,066.80.

In the deterministic analysis, the mean PAL rates in Table 1 and mean reoperation rates in Table 2 were used as clinical inputs. The average total initial VATS lobectomy costs were calculated separately for the PAL no-PAL groups by adding their corresponding stapler charges (Table 3) to the total inpatient costs (excluding stapler costs, Table 1). For any terminal nodes with reoperation, the average cost of reoperation was added. The deterministic analysis results are shown in Table 4. When compared to the MES strategy, using PES in VATS lobectomies resulted in savings of CNY2,753 per patient. The PES strategy also had lower re-operation rates within 6 months after discharge from the initial VATS lobectomy surgery (0.54% for PES group vs 0.63% for MES group). Thus, based on the deterministic CEA results, PES is the dominant strategy in VATS lobectomy, as it provides better clinical outcomes at lower total costs.

We investigated the model output stability using both one-way sensitivity analyses. In the one-way sensitivity analyses, all input variables were tested one at a time for 15% changes above and below the values used in the deterministic calculations while holding everything else constant (Table 5). The one-way sensitivity analysis outputs are plotted in Figure 2. PES remains the dominant strategy for all settings except for the scenarios of a 15% price increase for PES or a 15% price cut for MES.

A PSA was conducted to further test the robustness of CEA results. Except for stapler and cartridge prices, all variables were randomly drawn from their corresponding distributions. 10,000 simulation runs were performed in the PSA. The means and standard deviations for costs and re-operation rates are reported in Table 3. Figure 3 plots incremental costs vs incremental effectiveness (reduction in reoperation rates). The PSA runs demonstrated that the PES strategy dominated the MES strategy in 60% of all simulation runs. The means of the PSA results were also highly consistent with the deterministic calculation outputs, further supporting the stability of the CEA model conclusion.

Discussion

In this study on the cost-effectiveness comparison between PES and MES in VATS lobectomy surgeries, we found PES is superior to MES in both the reduction of costs and the reduction of re-operation risk. Our results showed that using PES to replace MES resulted in a net savings of CNY 2,753 per patient while also

achieving a reduction in reoperation rates. The sensitivity analysis demonstrated these conclusions were robust after considering the variability of input variables.

The advantages of VATS have been well documented in the literature(3, 8-12). Given the increasing prevalence of VATS, particularly in lung cancer treatment, staplers are now becoming one of the key enabling technologies. Compared to open surgeries, VATS lobectomy procedures must be performed in a more constrained operative space. The launch of powered endoscopic stapler devices marked a major milestone for innovation in endoscopic stapling technology. PES utilizes a motor for both staple firing and knife blade action. Even with regulatory agencies backing the reliability and safety of PES technology, the choice of using wound closure devices in VATS in many hospital systems in China is far from a simple choice based on clinical superiority alone. With an aging population, almost all major countries in the world are facing the challenges of balancing limited healthcare resources with the rapidly increasing demand for better healthcare. The delicate balance of resource and demand in healthcare is even harder to maintain for Chinese hospitals who need to meet both tough quality standards and cost control measures at the same time. Under this situation, hospital-based health technology assessments (HB-HTA) may play a major role to help optimize the efficiency of healthcare resource utilization.

Specific to the choice of PES or MES, the decision made by hospital administrations can have profound impacts. If the decision was made by device price comparison alone, MES may appear to have the potential of generating cost savings. Our comprehensive economic analysis that includes the total costs in the VATS lobectomies showed MES has higher costs and worse clinical outcomes. The driver for the PES advantage in the CEA model is a lower PAL rate. A reduction in peri-operative PAL rates led to lower surgical costs and lower re-operation rates. While the CEA model reported here is focused on the economic analysis, it is important to note the reduction in surgical complications will generate benefit beyond the cost savings. The literature has ample documented evidence that links PAL to several postoperative complications, from simple pulmonary atelectasis to severe pneumonia and pleural empyema(13). To our knowledge, this is the first cost-effectiveness analysis model built specifically for the comparison of PES and MES in VATS lobectomies. However, a retrospective study has been performed previously to compare PES and MES in VATS lobectomy by Miller et al(14). The findings from their analysis were consistent with our CEA model results: PES was associated with lower costs and better outcomes.

Even though the framework for performing health economic evaluations for medical devices is similar to those used for drugs, Michael Drummond et al(15) has clearly outlined the additional challenges for conducting economic analyses for medical devices. In the current CEA model, we have addressed these challenges using the best possible methods. Our analysis heavily relies on the analysis of real-world data collected in Chinese hospital systems and literature reports based on real-world data in China. The data used in our model was collected from 20 large tertiary hospitals, a reasonably large sample to represent the real-world situation of VATS lobectomy procedures in China. Both PES and MES were broadly available in these participating hospitals. It is reasonable to assume surgeons were familiar with both technologies.

Our research does have several limitations: 1. Multiple complications can happen in VATS. The model only explicitly considered PAL. While PAL is the most commonly occurred and impactful complication in VATS lobectomies, using PAL rates may not fully reflect the clinical performance difference between PES or MES; 2.

The choice of PES and MES captured in the data set was not randomized. The costs and outcomes extracted from the data are subject to baseline bias; 3. Our calculation did not account for the skill and experience difference of surgeons performing the VATS lobectomy; 4. All cost information was derived from real-world data with limited sample sizes. These values are subject to limited representativeness.

Conclusion

Our CEA analysis demonstrated using PES in VATS lobectomy surgeries to replace MES leads to lower total costs and lower re-operation rates for the hospitals in China. Compared to MES, PES is a cost-effective device for VATS lobectomies.

Declarations

Ethics approval and consent to participate

This study used de-identified retrospective data. The need for approval and consent was waived.

Consent for publication

Not applicable

Availability of data and materials

The data that support the findings of this study are available from Beijing Brainpower Pharma Consulting Co. Ltd, but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of Beijing Brainpower Pharma Consulting Co. Ltd.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

ZH and ZY both contributed to the research design, analysis review and manuscript editing. YH contributed to research design, model development, data analysis, manuscript draft and edit.

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Not applicable

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Tables

Table 1

Clinical Parameters used in the decision tree model. MES: manual endoscopic stapler; PES: powered endoscopic stapler; PAL: prolonged air leak; PSA: probabilistic sensitivity analysis

	Sample size	Cases	%	PSA Distribution
PAL incidence				
MES	95	24	25.3%	Beta
PES	109	7	6.4%	Beta
6-month Re-operation rate				
with PAL	297	3	1.01%	Beta
without PAL	1384	7	0.51%	Beta

Table 2

Model costs inputs and reoperation rates from EMR analysis. PAL=Prolonged Air Leak

Peri-operative cost item	PAL Group (N=297)		No-PAL Group (N=1,384)	
	Mean	SD	Mean	SD
Drug costs	19,293.56	10,972.89	13,123.00	6,243.33
Anesthetic fee	1,952.63	685.37	1,967.61	1,372.63
Nursing fee	793.56	636.54	492.54	274.92
Examination fee	2,621.15	2,337.47	2,788.74	1,919.55
Blood infusion fee	93.93	645.25	28.90	192.19
Room and board	1,133.72	910.92	890.72	630.55
Lab fee	8,868.37	4,984.36	6,854.67	4,251.76
Surgery fee	6,743.56	2,347.45	5,811.47	2,299.81
Treatment fee	3,915.94	3,287.16	2,435.46	1,772.12
Consumable materials (excluding Stapler and cartridges)	14,418.02	5,122.46	11,773.31	4,754.85
Miscellaneous fee	128.92	469.63	4,956.33	11,389.59
Total Inpatient Cost (Excluding Stapler and cartridge costs)	59,963.37	19,655.15	51,122.75	14,765.32

Table 3

Stapler and cartridge costs per VATS thoracotomy. MES: manual endoscopic stapler; PES: powered endoscopic stapler.

Item	Manufacturer	Product Code	Units per surgery	Cost (CNY)	Source for price
PES	Johnson & Johnson	PSEE60A	1.0	6,900	Guangzhou medical consumables procurement platform https://gpo.gzggzy.cn/home.html Last accessed on 12/12/2020
Cartridge for PES	Johnson & Johnson	GST60	6.47	3,800	
MES	Ruiqi	U12S/M/L	1.0	4,300	
Cartridge for MES	Ruiqi	R60	6.94	4,066	

Table 4

CEA analysis result. MES: manual endoscopic stapler; PES: powered endoscopic stapler; PAL: prolonged air leak; PSA: probabilistic sensitivity analysis; ICER: incremental cost-effectiveness ratio.

Strategy	Total Cost (CNY, Mean)	Cost (SD)	Re- operation rate (Mean)	Re- operation rate (SD)	Incremental Cost (MES-PES)	Incremental re- operation (MES-PES)	ICER (MES vs PES)
Deterministic results							
PES	83,486.85	-	0.538%	-			
MES	86,239.36	-	0.633%	-	2752.51	0.095%	Dominated
PSA results (10,000 runs)							
PES	83620.00	13857.79	0.539%	0.187%			
MES	86379.43	12059.46	0.633%	0.209%	2759.43	0.094%	Dominated

Table 5

Parameter information for sensitivity analysis

Variable Description	Base case Value	Low (-15%)	High (+15%)	PSA distribution
PES PAL rate	0.064	0.055	0.074	Beta
MES PAL rate	0.253	0.215	0.291	Beta
Re-operation rate for VATS lobectomy with PAL	0.010	0.009	0.012	Beta
Re-operation rate for VATS lobectomy without PAL	0.005	0.004	0.006	Beta
Total surgery cost with PAL (exclude stapler costs)	59,963	50,969	91,390	Gamma
Total surgery cost without PAL (exclude stapler costs)	51,123	43,454	74,946	Gamma
PES + cartridge costs	31,486	26,763	36,209	Constant
MES + cartridge costs	32,518	27,640	37,396	Constand
All inclusive re-operation costs	57,669	49,019	66,320	Gamma

Figures

Figure 1. Decision tree model structure. VATS: video-assisted thoracic surgery MES: manual endoscopic stapler; PES: powered endoscopic stapler; PAL: prolonged air leak; pwd_PAL_rate: probability of PAL using PES; man_PAL_rate: probability of PAL using MES; PAL_readm_rate: probability of re-surgery if index surgery has PAL; nonPAL_readm_rate: probability of re-surgery if index surgery has no PAL

Figure 1

Please See image above for figure legend.

Tornado Diagram - ICER PES vs. MES

Figure 2: Tornado plot of one-way sensitivity analysis results. Red and blue bars were calculated with high end and low end values of the input variables respectively.

Figure 2

Please See image above for figure legend.

Figure 3: Scatter plot of incremental cost effectiveness of PES vs MES.

Figure 3

Please See image above for figure legend.